COMMITTEE ON GOVERNMENT REFORM

CONGRESSMAN TOM DAVIS, CHAIRMAN

NEWS RELEASE

For Immediate Release
November 10, 2004

Contact: Robert White/Drew Crockett
(202) 225-5074

Davis Questions Merck & Co. on Vioxx

Washington, D.C. - House Government Reform Committee Chairman Tom Davis (R-VA) wrote yesterday to Raymond V. Gilmartin, Chairman, President and Chief Executive Officer of Merck & Co., seeking information in response to press reports that the company knew of the high risks associated with Vioxx as early as 2000 and that it may have pressured those in the medical community who questioned Vioxx's safety. The company decided to withdraw the drug from the marketplace on September 30th after it inadvertently discovered that the drug's use may increase the risk of heart attack and stroke.

"As the Committee continues to investigate FDA's approval and post-marketing surveillance of Vioxx, determining whether FDA adequately monitored the drug will be impossible without first grasping what Merck officials knew, when they knew it, and whether they fully shared their knowledge with FDA," Chairman Davis said.

A copy of today's letter follows:

November 9, 2004

Mr. Raymond V. Gilmartin
Chairman, President and Chief Executive Officer
Merck & Co., Inc.
One Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889-0100

Dear Mr. Gilmartin:

On September 30, 2004, Merck & Co., Inc. (Merck) announced a voluntary worldwide withdrawal of Vioxx (rofecoxib), an arthritis and acute pain medication. Merck stated that this decision was made based on data from a clinical trial study designed to evaluate the efficacy of Vioxx in preventing recurrence of colorectal polyps in patients with a history of colorectal adenomas. The study showed that after 18 months of treatment, patients taking Vioxx compared with those taking a placebo, showed an increased risk for cardiovascular events, such as heart attacks and stroke.

Subsequent to this announcement, many questions have been raised as to what Merck knew about the potential for increased risks of cardiovascular events, and when Merck knew of those risks. A November 1, 2004 *Wall Street Journal* article, entitled "Warning Signs: E-Mails Suggest Merck Knew Vioxx's Dangers at Early Stage," presents excerpts from Merck internal emails that suggest Merck was aware of these risks as early as 2000. Additional emails in the article state that Merck was instructing drug marketers to "dodge" questions concerning the cardiovascular risks associated with Vioxx, and pressured medical professionals and academic institutions who questioned the cardiovascular safety of Vioxx. A recent study published in *The Lancet* on November 5, 2004, presents a meta-analysis of Vioxx data and concludes that an increased risk for cardiovascular events was evident as early as 2000 and that Vioxx should have been withdrawn from the market several years earlier. Merck has stated publicly that the emails have been "taken out of context" and completely discount the study in *The Lancet*.

As you may be aware, this Committee is conducting an investigation into the Food and Drug Administration's (FDA) approval and post-marketing surveillance of Vioxx, and a review of the events leading up to Merck's withdrawal of Vioxx from the market. In light of recent news articles and published reports claiming company officials may have been aware of cardiovascular problems associated with the drug years before, we are also concerned with actions taken by Merck and whether full disclosure was provided to FDA. Therefore, we are requesting that, pursuant to Rules X and XI of the U.S. House of Representatives, you provide the Committee with the information requested below by Tuesday, November 23, 2004.

1. Identify all trials, studies or reports initiated by Merck relating to Vioxx, including any conducted outside the United States. This list should include, but not limited to, those trials, studies or reports for any New Drug Application (NDA) or Investigational New Drug (IND) Application, including any supplemental applications. For each such trial, study or report, provide the following information:

    a. The name of the author(s) and/or physician(s) that participated;
    b. The number of participants;
    c. The date it was initiated, completed and/or terminated. If terminated, explain the reasons behind the termination.
    d. A summary of the methodology, findings and conclusions;
    e. Whether any compensation or benefit, monetary or otherwise, was provided to any author and/or physician or participant; and
    f. A copy of all trials, studies or reports identified.

2. It is the understanding of the Committee that Merck employed the use of "data safety boards" (this term includes any boards intended to monitor safety) in trials and studies.

    a. In general, describe the method Merck uses to determine whether a trial or study should include a data safety board;
    b. Describe the method by which members of the data safety board are chosen and their relationship to Merck;
    c. With regard to Merck's VIGOR study, identify each member of the data safety board, each member's affiliation with Merck, and provide each member's curriculum vitae;
    d. With regard to Merck's VIGOR study, identify when the data safety board began involvement with the study and provide copies of all records between Merck and the data safety board;
    e. With regard to Merck's APPROVe study, identify each member of the data safety board, each member's affiliation with Merck, and provide each member's curriculum vitae; and
    f. With regard to Merck's APPROVe study, identify when the data safety board began involvement with the study and provide copies of all records between Merck and the data safety board.

3. All records provided to the February 2001 FDA Arthritis Advisory Committee, which met to review the safety of COX-2 inhibitors and data from the VIGOR clinical trial.

4. All records relating to the development of the printed label that accompanied prescriptions of Vioxx. This should include, but not be limited to, all communications with FDA, and those within Merck.

5. During the time period to reach agreement on the printed label that would accompany prescriptions of Vioxx, provide all records of communication provided to healthcare providers and pharmacists concerning the safety and efficacy of the drug.

6. The November 1, 2004 *Wall Street Journal* article, entitled "Warning Signs: E-Mails Suggest Merck Knew Vioxx's Dangers at Early Stage," presents excerpts from Merck internal e-mails that suggest that Merck was aware of cardiovascular risks from Vioxx as early as 2000. To better understand the allegations made in this article, and Merck's explanation of these allegations, provide the following:

    a. All presentations, training sessions, or materials given to Merck employees and agents who marketed Vioxx;
    b. The November 21, 1996, Merck memorandum that stated that a study that would prevent patients from using aspirin would result in substantially higher rates of cardiovascular incidents;

c. The February 25, 1997, email by Merck official Briggs Morrison, which argued that more thrombotic events would occur if patients could not take aspirin under the study; also identify Mr. Morrison's position at Merck;
d. The response from Alise Reicin, in which she wrote, "I just can't wait to be the one to present those results to senior management," or words to that effect;
e. The March 9, 2000, email from Dr. Edward Scolnick, which suggested that cardiovascular risks "are clearly there," or words to that effect;
f. All records relating to the Vioxx work or presentations made by Dr. Gurkirpal Singh of Stanford University;
g. All records relating to the Vioxx work or presentations made by Dr. Lee Simon of Beth Israel Deaconess Medical Center in Boston;
h. All records relating to the Vioxx work or presentations made by M. Thomas Stillman of the University of Minnesota; and
i. Any additional records that reflect or relate to Merck's claim that the internal emails described in the *Wall Street Journal* were taken out of context.

7. All records of communication between Merck and FDA regarding FDA's observational study to identify cardiovascular risks associated with the use of COX-2 inhibitors, including Vioxx, by patients in Kaiser Permanente of Northern California.

8. For the notification provided to FDA of the decision to withdraw Vioxx from the market, provide the following:

    a. The date when FDA was first notified of the decision;
    b. The date of each subsequent communication with FDA to explain the data from the APPROVe study;
    c. The name and title of each Merck employee who was involved in notifying FDA of the decision;
    d. All records provided to FDA regarding the notification and explanation of the decision to withdraw Vioxx from the market; and
    e. All records of communications between Merck and FDA regarding Vioxx, after FDA was notified of the withdrawal.

9. The VIGOR trial demonstrated a difference in the cardiovascular event rate between those patients taking Vioxx and those taking naproxen. Merck has maintained that the results of the VIGOR study were a result of naproxen having a cardioprotective effect. Provide all records that support this position, including, but not limited to, any analysis, trial, study, and/or report.

Sincerely,

Tom Davis
Chairman

###